THE COALITION FOR ANIMAL HEALTH

January 19, 1998

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Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1-23
Park Building
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket No. 97N-0217 (Proposals to Increase the Availability of Approved Animal Drugs Approvals for Minor Species and Minor Uses – Discussion Draft)

The Coalition For Animal Health is comprised of the major national trade associations representing the animal production, animal feed, and animal health products industries, as well as the veterinary profession. The Coalition was an active participant in negotiations leading to the enactment of the Animal Drug Availability Act of 1996 (ADAA), and we are pleased to comment on the agency's discussion draft of "Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses".

General Observations

Members of the Coalition appreciate the agency's commitment to the ADAA's intent of improving the availability of all animal drugs. It is clear from the draft that CVM has a sincere desire to make more minor species and minor use drugs available to the animals and their owners who need them. The Coalition, however, is concerned because elements of this discussion draft conflict with the Coalition's understanding of how the agency intended to approach the minor species/use availability question.

It is important to remember that CVM itself requested the ADAA provision requiring the agency to propose by April 1998 an overhaul of the minor species/use approval process. That provision replaced language in earlier versions of the bill that directly would have amended the Food, Drug and Cosmetic Act's treatment of minor species/use drugs. Congress agreed to CVM's request because it and the Coalition was assured that CVM had a strong vision and framework for overhauling the minor species/use approval process. The agency indicated during the bill's passage that it simply needed extra time to "flesh out" its minor species/use concepts and that most of its program could be implemented through regulatory, rather than statutory, changes.

The December 19 discussion draft lacks evidence of clear, cohesive vision. The materials made public to this point lead the Coalition to believe the agency in 1996 was not as advanced in its planning for a minor species/use strategy as we would have hoped. We have seen no evidence to date that the agency is in the process of giving shape and texture to a strategy that already was in the works in early 1996; rather, the discussion draft gives the impression that the agency still is trying to arrive at a

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strategy. This causes great concern to those Coalition members who voluntarily gave up the ADAA's original proposed changes to the minor species/use approval process; we now fear the plan proposed in April, 1998, will not be as well-thought-out and comprehensive as is necessary to effect meaningful change.

Coalition members also are deeply dismayed at the December 19 discussion draft's heavy reliance on congressional action to improve minor species/use availability. Of the nine major initiatives contemplated in the draft, eight require legislation before they can take effect. While the Coalition recognized from the outset some statutory changes might be necessary, we never expected legislation to comprise the vast majority of initiatives being considered by the agency. The Coalition is concerned that CVM is being overly timid about exercising authority available under existing statute. We fear the agency is reflexively seeking legislative authority to implement its initiatives rather than diligently exploring all available options for regulatory implementation.

If the agency intended from the outset to make legislative action the focus of its minor species/use initiative, it should have indicated this in 1996. Two outstanding legislative vehicles – the ADAA itself and the 1997 FDA reform bill – now have passed Congress, and a minor species/use initiative could have been included as part of either of those measures. Legislation is not easy to pass, and opportunities to amend the Food, Drug and Cosmetic Act do not present themselves on a daily basis. By making legislation the key component of its minor species/use program, and by failing to signal this to the Coalition when ideal legislative vehicles were available, the agency has diminished the program's chances of success.

Following are the Coalition's comments on several of the incentives outlined in the December 19 discussion draft.

Modification of Extra-label Provisions

The Coalition agrees with CVM that extra-label use alone is not the long-term solution to the minor species availability problem, but the Coalition unanimously believes minor species should be able, in carefully controlled instances, to receive drugs in an off-label fashion through feed. However, there are a variety of opinions within the Coalition about whether this is best achieved through amending AMDUCA, amending the veterinary feed directive (VFD) provisions of ADAA, issuing a Compliance Policy Guide or some combination of the above. Determining the best approach is a complex legal question and impossible to address in the short time frame allotted comments on this discussion draft. The Coalition will provide additional suggestions to the agency about the best legal approach for resolving this issue.

Removal of Disincentives

The Coalition is baffled by CVM's apparent desire to increase enforcement resources against unapproved minor species/use drugs and to amend the statute to make it easier to remove such drugs from the market. The Coalition does not understand the rationale behind making it easier to remove an unapproved minor species/use drug than to remove an unapproved major species/use drug. Until

such time as an effective new minor species/use approval process is producing a documented increase in the number of approved minor species/use drugs, enforcement resources targeted for the minor species/use market should be no more stringent than for other classes of drugs.

Coalition members will not support changing the standard for regulatory action against minor species/use drugs for the reasons outlined above and because we believe such a change might have unintended consequences for major species/use drugs. The Coalition does support changing regulations to ensure drug manufactures that an application for minor use indication on an approved drug will not "open up" that drug's existing approval for further review.

Enhancement of Existing Programs for Data Development

The Coalition can support all the initiatives outlined in this section, but we question the impact on the number of minor species/use approvals, with one reservation. Until we are certain the existing programs are adequately meeting the needs of food and fiber producing animals, we cannot support expanding the scope of the NRSP-7 program or creating a similar program for non-food and fiber producing animals, if that expansion or new program creation would reduce the level of resources going to food and fiber producing animals. We generally think it is unrealistic, even under improving federal budgetary conditions, to expect Congress to have sufficient funds to expand these programs. The Coalition reiterates its concern about CVM over-relying on impractical legislative solutions to address the minor species/use problem.

Incentives to Pursue Minor Use Drug Approvals

The Coalition can support all three of the initiatives under this section, and we commend the agency for suggesting one – negotiating shorter timeframes for review of a major product for minor use – that needs no congressional action.

Creation by Statute of a "Minor Use Animal Drug Program"

Aside from our oft-repeated concerns about over-reliance on statutory change, the first part of this proposal is particularly frustrating because this was the general direction in which the original versions of the ADAA were headed. These types of provisions were removed from the ADAA at CVM's request. Obviously, the Coalition supports the proposal, but we are very dismayed that it has taken almost three years to return to virtually the same point where we were when the ADAA originally was introduced.

The Coalition supports creation of a minor species/use work unit within CVM; in fact, the Coalition was under the impression CVM already has such a unit. If it does not, then the agency should give some thought to how this unit might be funded.

Conditional Drug Approval for Minor Uses Involving Non-Food Animals

The Coalition is not comfortable with the concept of conditional approvals per se, but believes many

of the concepts outlined in this section could be used as the basis for a vastly streamlined approval process. We also believe that at least some of this streamlining does not need to be contingent on legislative action. Under no circumstances, though, will the Coalition support programs of the type outlined in this section if they exclude food-producing animals.

Alternate Approval Standard/Expert Review Panels

These proposals can be supported by the Coalition, but only if they are devised in a way to include food-producing animals.

International Harmonization

The Coalition supports the proposals in this section and commends the agency for having this initiative be comprised entirely of regulatory actions.

The Coalition very much appreciates the opportunity to comment on this docket. Our specific concerns and criticisms in no way diminish our commitment to working with CVM's to improve the availability of minor species/use drugs. We look forward to working with the agency for the successful implementation of this and all other provisions of the ADAA. Please do not hesitate to contact us if we can be of further assistance.

Respectfully submitted,

THE COALITION FOR ANIMAL HEALTH
American Farm Bureau Federation
American Feed Industry Association
American Sheep Industry Association
American Veterinary Medical Association
Animal Health Institute
National Broiler Council
National Cattlemen's Beef Association
National Pork Producers' Council
National Turkey Federation
United Egg Association
United Egg Producers